REMARKS

Status of the Claims

Claims 1-7 are currently pending in the application. Claims 1, 3 and 5 stand rejected. Claims 2, 4, 6 and 7 are withdrawn as being drawn to a non-elected invention. Claims 1, 5 and 6 have been amended without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendments to claims 1, 5 and 6 are to conform the claims more closely to US practice and are inherently supported by the specification and merely clarify that the cultures claimed are isolated or purified cultures, as suggested by the Examiner. Reconsideration is respectfully requested.

Objections to the Abstract

The Examiner objects to the abstract because the abstract is too long. (*See*, Office Action at page 2, hereinafter, "Office Action"). The Examiner is respectfully referred to the MPEP at § 608.01(b), and 37 C.F.R. § 1.72, which state, in part, "The sheet or sheets presenting the abstract ..." These sources also provide that the Abstract of the Invention may not exceed 150 words in length. Applicants note that the present Abstract of the Invention is clearly less than 150 words in length.

However, in an attempt to address the Examiner's concerns, Applicants have submitted herein an amendment to the abstract which reduces the size of the structures of the macrolides of formulas I and II so that the Abstract should be contained on a single page. Clearly, no new matter is introduced into the specification by way of the amendment to the Abstract since nothing, other than the size of the structure of formula II, has been changed by the amendment.

Reconsideration and withdrawal of the objection to the Abstract of the Invention are respectfully requested.

Objections to the Specification

The Examiner objects to the specification for containing sequences which do not comply with the Sequence Rules. (*Id.*). Specifically, the Examiner states that pages 8 and 9 of the specification disclose two tables, Tables 1 and 2, which include sequences. However, the same tables also include a first column which is called "Sequence No." The Examiner also objects to the specification for reciting an embedded hyperlink.

Although Applicants believe that Tables 1 and 2 are fully compliant with the Sequence Rules, as remarked above, to expedite prosecution, these Tables have been amended to more clearly indicate that the first column is the sequence identifier number.

Additionally, Applicants note that in every instance where UNISON and EUSAN-MEAT are recited in the specification, they are capitalized. Applicants have also amended the specification to edit the embedded hyperlink as requested by the Examiner.

None of these amendments enter new matter into the specification. The amendments are fully supported by the as-filed specification. The amendments are merely clarifications which address grammatical or typographical informalities.

Reconsideration and withdrawal of the objection to the specification are respectfully requested.

Rejections Under the Obviousness-Type Double Patenting Doctrine

Claims 1, 3 and 5 are provisionally rejected under the judicial doctrine against obviousness-type double patenting, over the disclosure of the co-pending application U.S. Patent Application Serial No. 11/213,962. (*See*, Office Action, at pages 3-4). The Examiner is respectfully requested to follow the procedure that is described in M.P.E.P. § 804(I)(B)(1), and reads as follows:

> If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.
>
> If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Accordingly, the Examiner is respectfully requested to issue a Notice of Allowance in this case and to address any possible double patenting issues in the co-pending applications.

Furthermore, Applicants note that the invention disclosed in U.S. Patent Application Serial No. 11/213,962 requires a fermentation step to obtain pladeinolide B or pladienolide D. However, in contrast, the '962 application fails to disclose or suggest hydrooxidation (-OH) of

the fermentation product at the 16-position. The presently claimed invention includes production of a macrolide compound 11107D of formula (II) having a hydroxyl (OH) group at the 16 position, by starting from a macrolide compound 11107B of formula (I) which has no hydroxyl (OH) group at the 16 position. The production is performed by incubation with a microorganism, as claimed.

Rejections Under 35 U.S.C. § 101

Claim 5 stands rejected under 35 U.S.C. § 101 because they allegedly are directed to non-statutory subject matter. (*See*, Office Action, at pages 4-5). Applicants traverse the rejection.

The Examiner states that claim 5 encompasses a product of nature, i.e. *Streptomyces* sp. AB-1704 strain. Applicants note that claims 5 and 6 have both been amended by way of this Amendment to recite, in part, "An isolated or purified culture of ..."

Therefore, reconsideration and withdrawal of the rejection of claim 5 are respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 3 and 5 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement support in the specification. This rejection concerns the biological deposit of the strains recited in the claims. The Examiner wishes to ascertain whether the strains were deposited in a Budapest Treaty International Depository Authority facility. Applicants note that the International Patent Organism Depositary (IPOD) and the National Institute of Advanced

Industrial Science and Technology (AIST) are recognized official depository authorities in Japan. (*See*, present specification at, for instance, pages 5-6, and MPEP § 2405).

Furthermore, Applicants assure the Examiner that the deposit will be available to the public according to 37 C.F.R. § 1.808, during the pendency of the present application upon request by proper parties determined to be entitled to such access by the Director under 37 C.F.R. § 1.14 and 35 U.S.C. § 122, and that once allowed, all such restrictions on access to the samples will be removed.

Therefore, reconsideration and withdrawal of the rejection of claim 5 as lacking enablement support are respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 3 and 5 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (*See*, Office Action, at page 8). Applicants traverse the rejection.

The Examiner states that claims 1 and 5 recite the phrase "strains having the ability of transforming a macrolide compound." The Examiner states that this phrase in unclear. The Examiner asks how this ability is determined.

However, claim 1 recites at least three distinct steps which allow determination of whether the strain encompassed by the claims has the ability to transform the macrolide compound. Furthermore, the specification clearly shows how one of skill in the art can determine whether the macrolide compound has been transformed. For instance, the Examiner's attention is respectfully directed to Examples 3-5, 7 and 8 of the present specification, all of

which provide clear instructions for determining whether a strain has the capability to transform the macrolide. Additionally, the Examples cited utilize routine procedures commonly known to one of skill in the art, such as chromatography and bacterial culturing.

Reconsideration and withdrawal of the indefiniteness rejection of claims 1, 3 and 5 are therefore respectfully requested.

Rejections Under 35 U.S.C. § 102(e)

Claims 1, 3 and 5 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Kotake et al., U.S. Patent No. 7,256,178 (hereinafter, "Kotake et al."). (*See*, Office Action, at pages 9-10). Applicants traverse the rejection.

The Examiner states that Kotake et al. disclose a method of producing a macrolide compound encompassed by the present claims. However, Kotake et al. claims priority to PCT/JP03/09753, which was published as WO 04/011661 on February 5, 2004. The International Application PCT/JP03/09753 was filed after November 29, 2000, designated the US, but was not published in the English language. Therefore, the effective US filing date of Kotake et al. is January 28, 2005. The effective U.S. filing date of the present application is November 27, 2003. Thus, Kotake et al. is not prior art.

Reconsideration and withdrawal of the anticipation rejection of claims 1, 3 and 5 are respectfully requested.

CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: May 12, 2008

Respectfully submitted,

By _____
Marc S. Weiner #21,066
Registration No.: 32,181
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicants

Attachments: Abstract (clean copy)